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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,921

09/30/2005

Gunter Ziegler

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BIO TECHNOLOGY LAW GROUP
C/O PORTFOLIOIP
P.O. BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

2876

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,921	Applicant(s) ZIEGLER ET AL.	
	Examiner Suezu Ellis	Art Unit 2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2-21 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,22,23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

Response to Arguments

Applicant's arguments with respect to claims 1, 22, 23 and 25-30 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 16, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Claim 29 provides for the use of the implant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 22 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuhara et al. (US 2001/0002994) in view of Edwards et al. (US 4,906,466) and Bechert et al. (US 6,984,392).

With respect to claims 1, 22 and 28, With respect to claims 1 and 22, Masuhara et al. discloses titanium oxide coating on an implant prepared by adding a preparation containing an organic solvent and an organometallic titanium oxide precursor, and applying the preparation prepared onto an implant, and drying the coating [0033], [0038], [0101], [0132], [0146]. Masuhara et al. further discloses the preparation can include metal salts of silver, copper or zinc to exert an antimicrobial or antibacterial effect under physiological conditions [0136]. (Examiner notes that it is well known in the art that metal salts, such as salts of silver, release metal ions (silver ions), as demonstrated by Edwards et al. – col. 3, lines 32-63). However, Masuhara et al. fails to expressly disclose the metal salts are dispersed homogeneously in the preparation. Bechert et al. teaches a coating for implants comprising homogeneously dispersing silver in a matrix material in order to contribute to the amount of silver ions released always being the same at all sites on the surface of the material [0019]. It would have

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been obvious to one of ordinary skill in the art to homogenously disperse the metal salts in the preparation in order to contribute to the amount of silver ions released always being the same at all sites on the coating, as taught by Bechert et al.

With respect to claim 26, the modified Masuhara et al. discloses the metal salts (metal ions) contained in the titanium oxide is in a concentration that initially has an antibacterial effect [0136], however fails to expressly disclose the metal salts (metal ions) being biocompatible. However, one of ordinary skill in the art would appreciate the silver salts to be biocompatible in order to provide the desired antimicrobial activity in vivo, and since the composition of the modified Masuhara et al. is used for dental purposes in the mouth of a patient, the silver salts (silver ions) are considered to be biocompatible.

With respect to claim 27, the modified Masuhara et al. discloses the concentration of the metal salts (metal ions) in the titanium oxide coating is 1-20% by weight [0136].

With respect to claim 29, the modified Masuhara et al. discloses the implant is for mouths [0002], [0146], thus is considered to be implanted into a patient.

With respect to claim 30, the modified Masuhara et al. discloses the preparation further comprises water and/or an acid [0132].

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuhara et al. in view of Edwards et al. and Bechert et al. and further in view of Pratt et al. (US 4,849,223).

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With respect to claim 23, the modified Masuhara et al. addresses all the limitations of claim 22, and further discloses the composition contains a metal component (silver salt) and inhibits the growth of bacteria around the surface of the substrate to which is has been applied [0136]. However, the modified Masuhara et al. fails to expressly disclose the metal ions contained in the coating can be dissolved out of the coating into the surrounding medium under physiological conditions. Nevertheless, it is known in the art that when used in coatings of biomedical devices, metal ions contained in the coating can be dissolved out of the coating into the surrounding medium under physiological conditions, as taught by Pratt et al. (col. 2, lines 33-41). Therefore, the metal ions contained in the coating of Masuhara et al. is considered to be able to be dissolved out of the coating into the surrounding medium under physiological conditions.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuhara et al. in view of Edwards et al. and Bechert et al. and further in view of Sahota (US 2003/0181973).

With respect to claim 25, the modified Masuhara et al. discloses the titanium oxide coating layer comprises metal salts homogeneously dispersed in the coating, as described above with reference to claim 1. However, the modified Masuhara et al. fails to expressly disclose the implant comprises a plurality of the titanium oxide coating layers. It is known in the art for implants to have a plurality of coating layers in order to control the elution profile of the desired drug, as demonstrated by Sahota [0086]. It

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would have been obvious to one of ordinary skill in the art to provide a plurality of titanium oxide coating layers in order to elute the metal ions for a longer period of time, as desired [0086].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Scales et al. (US 4,615,705) discloses an antimicrobial surgical implant having a bioerodable metallic silver component.

Galley et al. (US 5,688,492) discloses an oral hygiene composition comprising titanium dioxide suspended in an aqueous solution of silver nitrate and reacted with silver chloride to precipitate silver chloride on the titanium dioxide.

Capelli (US 6,093,414) discloses a silver-based antimicrobial composition.

Ichimura et al. (US 5,147,686) discloses a method of making titanium oxide powder having an antimicrobial metal.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615